

### **REMARKS**

Applicants provisionally elect the claims of Group I and Species C with traverse.

#### **Election of Groups with Traverse**

In the Office Action mailed on April 23, 2007, the claims have been restricted under 35 U.S.C. § 121 and 372 as follows:

- Group I: Claims 24-54 drawn to a method of treating or preventing estrogen-sensitive tumours in a mammal comprising administering, with or without GnRH composition, a therapeutically effective amount of an estrogenic component.
- Group II: Claim 55-62 drawn to a product containing a pharmaceutical composition, a drug delivery system and a pharmaceutical kit.

Particularly, the Examiner asserts that Groups I and II do not relate to the same inventive concept under PCT Rule 13.1 and 13.2. To support a restriction requirement under PCT Rules 13.1 and 13.2, the Examiner must show that the groups lack the same or corresponding special technical feature. A special technical feature is a technical feature that defines the contribution of the claimed invention (as a whole) over the prior art. MPEP § 1850.

The Applicants respectfully traverse this rejection because Group II is not suitable for use in a method of inhibiting conception similar to the method described in Spicer et al. (United States Patent No. 5,211,952) because the claimed aromatase inhibitors are not used in oral contraceptives. Therefore, Group II cannot be directed to a product for inhibiting conception. Thus, there is no reason of record distinguishing the special technical features of Groups I and II. For this reason, the Applicants respectfully request that the restriction requirement be withdrawn and that Groups I and II be examined on the merits.

**Election with Traverse of Species**

The Restriction Requirement further asserts that the application contains more than one species of a generic claim, and that the species lack unity of invention under PCT Rule 13.1. The Examiner identifies the following species:

- Species A: Estrogen-sensitive tumours, for example, breast cancer or uterine cancer as claimed in claims 25, 35, and 45 (claims 24, 33, 35, 43, 45 and 53);
- Species B: Aromatase inhibitors as claimed in claims 34, 35, 54 and 55 (claims 34, 35, 54 and 55);
- Species C: Estrogen component represented by the formula claimed in claims 25, 35, 45 or 55 (claims 25-28, 35-38, 45-48 and 55-58); and
- Species D: Estrogen component elected as described in Group C with or without administration of a GnRH composition as claimed in claims 25, 35, 45, or 55 (claims 25-28, 35-38, 45-48 or 55-58).

Applicants respectfully traverse the restriction of species for the following reasons. First and foremost, the restriction of species fails to cite any reason why the restriction proper. Under MPEP § 803, the Examiner has the burden to provide such reasons. In this case, the Examiner has only asserted a conclusion, that “these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1,” and has failed to provide any reason to support this conclusion. Therefore, the Examiner has failed to make a *prima facie* showing that a restriction of species is proper. The Examiner has likewise failed to meet the burden as stated in MPEP § 808.02 of establishing that there is a serious burden on the Examiner if a restriction is not required. For these reasons, this restriction requirement should be withdrawn.

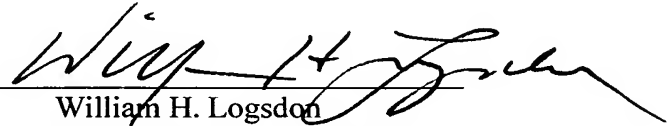
Notwithstanding the above, the restriction of species is improper because Species A through D share the same special technical feature since they all ultimately require an estrogenic component as recited in independent claims 25 and 55.

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### **CONCLUSION**

Accordingly, the Applicants respectfully request that the Restriction Requirement be withdrawn, that pending claims 25-62 be examined on the merits, and that a Notice of Allowance be issued. Should the Examiner have any questions or would like to discuss this further, the Examiner is invited to contact the Applicants' undersigned representative by telephone at 412-471-8815.

Respectfully submitted,  
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